ISO 9000 - Quality Management and Quality Assurance Standards - Guidelines for Selection and Use

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ABSTRACT: This document is a copy of ISO 9000, first edition, 1987 (E). It is reproduced, with permission from the International Organization for Standardization, for use within Digital Equipment Corporation. This standard clarifies the distinctions and interrelationships among the principal quality concepts (see clause 4), and provides guidelines for the selection and use of a series of international standards on quality systems that can be used for internal quality management (ISO 9004) and for external quality assurance (ISO 9001, ISO 9002, ISO 9003). (See clauses 5 to 8 inclusive.)

APPLICABILITY: This document is included in the ISO 9000 series of standards. It is referenced in ISO 9001 through 9003 and is included here as a reference document.

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INTERNATIONAL STANDARD

ISO 9000 - Quality management and quality assurance standards - Guidelines for selection and use

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75% approval by the member bodies voting.

International Standard ISO 9000 was prepared by Technical Committee ISO/TC 176, *Quality assurance*.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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ISO 9000 - Quality management and quality assurance standards - Guidelines for selection and use

0 Introduction

A principal factor in the performance of an organization is the quality of its products or services. There is a worldwide trend towards more stringent customer expectations with regard to quality. Accompanying this trend has been a growing realization that continual improvements in quality are often necessary to achieve and sustain good economic performance.

Most organizations - industrial, commercial or governmental - produce a product or service intended to satisfy a user's needs or requirements. Such requirements are often incorporated in "specifications". However, technical specifications may not in themselves guarantee that a customer's requirements will be consistently met, if there happen to be any deficiencies in the specifications or in the organizational system to design and produce the product or service. Consequently, this has led to the development of quality system standards and guidelines that complement relevant product or service requirements given in the technical specifications. The series of International Standards (ISO 9000 to ISO 9004 inclusive) embodies a rationalization of the many and various national approaches in this sphere.

The quality system of an organization is influenced by the objectives of the organization, by the product or service and by the practices specific to the organization, and, therefore, the quality system varies from one organization to another.

A cross-reference list of quality system elements is given in the annex for information.

1 Scope and field of application

The purposes of this International Standard are

a. to clarify the distinctions and interrelationships among the principal quality concepts (see clause 4), and

b. to provide quidelines for the selection and use of a series of International Standards on quality systems that can be used for internal quality management purposes (ISO 9004) and for external quality assurance purposes (ISO 9001, ISO 9002 and ISO 9003) (see clauses 5 to 8 inclusive).

NOTE

It is not the purpose of this series of International Standards (ISO 9000 to ISO 9004 inclusive) to standardize quality systems implemented by organizations.

2 References

ISO 8402, *Quality - Vocabulary.*

ISO 9001, *Quality systems - Model for quality assurance in design/development, production, installation and servicing.* [1]

ISO 9002, *Quality systems - Model for quality assurance in production and installation.* [1]

ISO 9003, *Quality systems - Model for quality assurance in final inspection and test.* [1]

ISO 9004, *Quality management and quality system elements - Guidelines.* [1]

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 apply. Five key terms and definitions have been taken from ISO 8402 and included in this International Standard because of their importance in the proper use of this International Standard.

3.1 quality policy: The overall quality intentions and direction of an organization as regards quality, as formally expressed by top management.

NOTE

The quality policy forms one element of the corporate policy and is authorized by top management.

3.2 quality management: That aspect of the overall management function that determines and implements the quality policy.

NOTES:

1. The attainment of desired quality requires the commitment and participation of all members of the organization whereas the responsibility for quality management belongs to top management.
2. Quality management includes strategic planning, allocation of resources and other systematic activities for quality, such as quality planning, operations and evaluations.

3.3 quality system: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

NOTES:

1. The quality system should only be as comprehensive as needed to meet the quality objectives.
2. For contractual, mandatory and assessment purposes, demonstration of the implementation of identified elements in the system may be required.

[1] The cross-references in the annex to specific clauses and sub-clauses in this series of International Standards apply to the first editions published in 1987.

3.4 quality control: The operational techniques and activities that are used to fulfill requirements for quality.

NOTES:

1. In order to avoid confusion, care should be taken to include a modifying term when referring to a sub-set of quality control, such as "manufacturing quality control", or when referring to a broader concept, such as "company-wide quality control".
2. Quality control involves operational techniques and activities aimed both at monitoring a process and at elimination causes of unsatisfactory performance at relevant stages of the quality loop (quality spiral) in order to result in economic effectiveness.

3.5 quality assurance: All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

NOTES:

1. Unless given requirements fully reflect the needs of the user, quality assurance will not be complete.
2. For effectiveness, quality assurance usually requires a continuing evaluation of factors that affect the adequacy of the design or specification for intended applications as well as verifications and audits of production, installation and inspection operations. Providing confidence may involve producing evidence.
3. Within an organization, quality assurance serves as a management tool. In contractual situations, quality assurance also serves to provide confidence in the supplier.

4 Principal concepts

An organization should seek to accomplish the following three objectives with regard to quality:

a. The organization should achieve and sustain the quality of the product or service produced so as to meet continually the purchaser’s stated or implied needs.

b. The organization should provide confidence to its own management that the intended quality is being achieved and sustained.

c. The organization should provide confidence to the purchaser that the intended quality is being, or will be, achieved in the delivered product or service provided. When contractually required, this provision of confidence may involve agreed demonstration requirements.

The relationship of the concepts the definitions of which are quoted in clause 3 is illustrated in the figure; this figure should not, however, be interpreted as a rigid model.

5 Characteristics of quality system situations

This series of International Standards on quality systems is intended to be used in two different situations: contractual and non-contractual.

In both these situations, the supplier's organization wants to install and maintain a quality system that will strengthen its own competitiveness and achieve the needed product quality in a cost-effective way.

In addition, in the contractual situation, the purchaser is interested in certain elements of the supplier's quality system which affect the supplier's ability to produce consistently the product or service to its requirements, and the associated risks. The purchaser therefore contractually requires that certain quality system elements be part of the supplier's quality system.

A single supplier will often be involved in situations of both types. The supplier may purchase some materials or components from standard inventory without contractual quality assurance requirements, and purchase others with contractual quality assurance requirements. The same supplier may sell some products in non-contractual situations and others in contractual situations.

6 Types of International Standards on quality systems

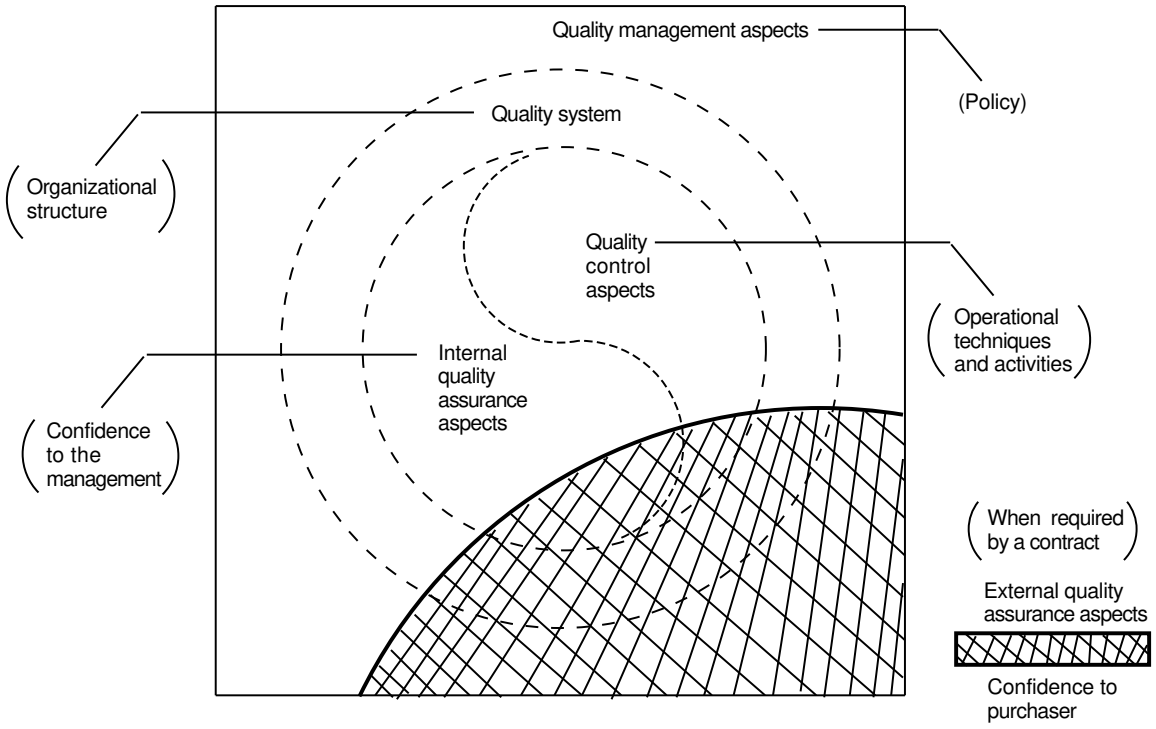
As indicated in clause 1, the following two types of standards, which embody the needs of the different situations classified in clause 5, are presented in this series of ISO International Standards on quality systems:

a. ISO 9004 (together with this International Standard) gives guidance to all organizations for quality management purposes.

b. ISO 9001, ISO 9002 and ISO 9003 are used for external quality assurance purposes in contractual situations.

7 Use of International Standards on quality systems for quality management purposes

After this International Standard has been consulted, reference should be made to ISO 9004 in order to develop and implement a quality system and to determine the extent to which each quality system element is applicable.



NOTES

1. The elements that comprise a quality system are listed in the annex.

2. Activities aimed at providing confidence to the management of an organization that the intended quality is being achieved are often called "internal quality assurance".

3. Activities aimed at providing confidence to the purchaser that the supplier's quality system will provide a product or service that will satisfy the purchaser's stated quality requirements are often called "external quality assurance".

Figure – Relationship of concepts

ISO 9004 provides guidance on the technical, administrative and human factors affecting the quality of products or services, at all stages of the quality loop from detection of need to customer satisfaction. Throughout ISO 9004, emphasis is placed on the satisfaction of the customer's need, the establishment of functional responsibilities and the importance of assessing (as far as possible) the potential risks and benefits. All these aspects should be considered in establishing and maintaining an effective quality system.

8 Use of International Standards on quality systems for contractual purposes

8.1 General

After this International Standard has been consulted, the purchaser and supplier should refer to ISO 9001, ISO 9002 and ISO 9003 to determine which of these International Standards is most relevant to the contract, and what specific adaptations, if any, have to be made.

The selection and application of a model for quality assurance appropriate to a given situation should provide benefits to both purchaser and supplier. Examining the risks, costs and benefits for both parties will determine the extent and nature of reciprocal information and the measures each party must take to provide adequate confidence that the intended quality will be achieved.

8.2 Selection of model for quality assurance

8.2.1 General

As indicated in the introduction to each of these three International Standards, certain quality system elements have been grouped into each of three distinct models based on the "functional or organizational capability" required of a supplier for the product or service:

a. **ISO 9001:** for use when conformance to specified requirements is to be assured by the supplier during several stages which may include design/development, production, installation and servicing.

b. **ISO 9002:** for use when conformance to specified requirements is to be assured by the supplier during production and installation.

c. **ISO 9003:** for use when conformance to specified requirements is to be assured by the supplier solely at final inspection and test.

8.2.2 Selection procedure

The model should be selected by systematic consideration of the factors described in 8.2.3 with due attention to the economic factor.

8.2.3 Selection factors

In addition to the functional criteria detailed in 8.2.1 (a) to 8.2.1 (c), the following six factors are considered to be fundamental for selecting the appropriate model for a product or service:

a. Design-process complexity.

   This factor deals with difficulty of designing the product or service if such product or service has yet to be designed.

b. Design maturity.

   This factor deals with the extent to which the total design is known and proven, either by performance testing or field experience.

c. Production-process complexity.

   This factor deals with

   1. The availability of proven production processes;
   2. The need for development of new processes;
   3. The number and variety of processes required;
   4. The impact of the process(es) on the performance of the product or service.

d. Product or service characteristics.

   This factor deals with the complexity of the product or service, the number of interrelated characteristics, and the criticality of each characteristic for performance.

e. Product or service safety.

   This factor deals with the risk of the occurrence of failure and the consequences of such failure.

f. Economics.

   This factor deals with the economic costs, to both supplier and purchaser, of the preceding factors weighed against costs due to nonconformities in the product or service.

8.3 Demonstration and documentation

The quality system elements should be documented and demonstrable in a manner consistent with the requirements of the selected model.

Demonstration of the quality system elements refers to

a. adequacy of the quality system (e.g. in design, production, installation and servicing);

b. capability to achieve product or service conformity with the specified requirements.

The nature and degree of demonstration may vary from one situation to another in accordance with such criteria as

a. the economics, uses and conditions of use of the product or service;

b. the complexity and innovation required to design the product or service;

c. the complexity and difficulty of producing the product or service;

d. the ability to judge product quality and fitness for use on the basis of final product test alone;

e. the safety requirements of the product or service;

f. the past performance of the supplier.

Documentation may include quality manuals, descriptions of quality-related procedures, quality system auditing reports and other quality records.

8.4 Pre-contract assessment

Assessments of a supplier's quality system are utilized prior to a contract to determine the supplier's ability to satisfy the requirements of ISO 9001, ISO 9902 or ISO 9003 and, when appropriate, supplementary requirements. In many cases, assessments are performed directly by the purchaser.

By agreement between purchaser and supplier, pre-contract assessment may be delegated to an organization independent of both contracting parties. The number or the extent of assessments can be minimized by using ISO 9001, ISO 9002 or ISO 9003 and by recognizing previous assessments carried out in accordance with these International Standards by the purchaser or by an agreed independent assessing organization.

8.5 Contract preparation aspects

8.5.1 Tailoring

Experience has shown that with a small fixed number of International Standards available, one of the International Standards can be selected that will meet needs adequately for almost any situation. However, on occasions, certain quality system elements called for in the selected International Standard may be deleted and, on other occasions, elements may be added. If this should prove necessary, it should be agreed between the purchaser and the supplier, and should be specified in the contract.

8.5.2 Review of contractual quality system elements

Both parties should review the proposed contract to be sure that they understand the quality system requirements and that the requirements are mutually acceptable considering the economics and risks in their respective situations.

8.5.3 Supplementary quality assurance or quality system requirements

There may be a need to specify supplementary requirements in the contract, such as quality plans, quality programmes, quality audit plans, etc.

8.5.4 Technical requirements

The technical requirements of the product or service are defined in the technical specification of the contract.

Annex

Cross–reference list of quality system elements

(This annex is given for information purposes and does not form an integral part of the standard.)

Clause (or sub–clause) No. in ISO 9004	Title	Corresponding clause (or sub–clause) Nos. in ISO 9001	ISO 9002	ISO 9003
4	Management responsibility	4.1 ●	4.1 ◐	4.1 ○
5	Quality system principles	4.2 ●	4.2 ●	4.2 ◐
5.4	Auditing the quality system (internal)	4.17 ●	4.16 ◐	–
6	Economics – Quality–related cost considerations	–	–	–
7	Quality in marketing (Contract review)	4.3 ●	4.3 ●	–
8				
9	Quality in specification and design (Design control)	4.4 ●	–	–
9	Quality in procurement (Purchasing)	4.6 ●	4.5 ●	–
10	Quality in production (Process control)	4.9 ●	4.8 ●	–
11	Control of production	4.9 ●	4.8 ●	–
11.2	Material control and traceability (Poduct identification and traceability)	4.8 ●	4.7 ●	4.4 ◐
11.7	Control of verification status (Inspection and test status)	4.12 ●	4.11 ●	4.7 ◐
12	Product verification (Inspection and testing)	4.10 ●	4.9 ●	4.5 ◐
13	Control of measuring and test equipment (Inspection, measuring and test equipment)	4.11 ●	4.10 ●	4.6 ◐
14	Nonconformity (Control of nonconforming product)	4.13 ●	4.12 ●	4.8 ◐
15	Corrective action	4.14 ●	4.13 ●	–
16	Handling and post–production fuctions (Handling storage packaging and delivery)	4.15 ●	4.14 ●	4.9 ◐
16.2	After–sales servicing	4.19 ●	–	–
17	Quality documentation and records (Document control)	4.5 ●	4.4 ●	4.3 ◐
17.3	Quality records	4.16 ●	4.15 ●	4.10 ◐
18	Personel (Training)	4.18 ●	4.17 ◐	4.11 ○
19	Product safety and liability	–	–	–
20	Use of statistical methods (Statistical techniques)	4.20 ●	4.18 ●	4.12 ◐
–	Purchaser supplied product	4.7 ●	4.6 ●	–

KEY

● **Full requirement**
◐ **Less stringent than ISO 9001**
○ **Less stringent than ISO 9002**
– **Element not present**

NOTES

1. The clause (or sub–clause) titles quoted in the table above have been taken from ISO 9004; the titles given in parentheses have been taken from the corresponding clauses and sub–clauses in ISO 9001, ISO 9002 and ISO 9003.

2. Attention is drawn to the fact that the quality system element requirements in ISO 9001, ISO 9002 and ISO 9003 are in many cases, but not in every case, identical.

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